DEVELOPMENT OF THE CHROMIUM PUBLIC HEALTH GOAL

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Purpose of this Presentation

- Explain the general process for developing Public Health Goals (PHGs)
- Discuss chromium toxicity
- Discuss why we based our PHG on a level that protects against cancer
- Describe the meaning of the PHG

PHGs for Chemicals in Drinking Water

- Established by the California Safe Drinking Water Act of 1996 (HSC Sec. 116365)
- OEHHA required to perform risk assessments and publish Public Health Goals for drinking water contaminants
- PHGs must be based exclusively on public health considerations
- PHG documents are posted on the web at: http://www.oehha.ca.gov

PHGs are Being Developed:

- For chemicals with an established Maximum Contaminant Level (MCL)
- When requested by the California Department of Health Services or the legislature
- In this case an MCL exists for total chromium, not hexavalent chromium

Public Health Goals (PHGs) are:

- Estimates of chemical levels in drinking water that would pose no significant health risk over a lifetime of exposure
- Determined through a comprehensive literature review and scientific evaluation, according to standard risk assessment procedures
- Subject to extensive internal and external scientific peer review and public review and comments

Public Health Goals (PHGs) are:

- Non-regulatory guidance values, considering only health effects
- To be used by California DHS as one of the inputs for setting MCLs for chemicals in drinking water
- Information on health risk levels, which can be used to determine health protective regulatory values and guide risk managers

Public Health Goals (PHGs) are:

- For protection against cancer, the PHG is the level estimated to cause no more than one cancer case in one million people exposed for a lifetime
  - One in a million (a 10^{-6} risk level) is considered to be an extremely small or negligible risk level
- For protection against non-cancer effects, the PHG is a concentration at which no toxic effects are expected, including an adequate margin of safety

Public Health Goals (PHGs) are:

- Protective of sensitive populations, considering other contaminants and all exposure routes
- Allowing for uncertainty; if information is inadequate to establish a safe level, the PHG may be set at zero
- To be re-evaluated at least every five years, to account for new information or risk assessment methods

Primary Environmental Forms of Chromium

- **Trivalent chromium (Cr III)**
  - Not very toxic
  - An essential dietary nutrient
- **Hexavalent chromium (Cr VI)**
  - The most toxic form of chromium
  - The primary basis for our health levels for chromium

Major Toxic Effects of Hexavalent Chromium

- Multiple effects after large single doses, incl. cytotoxicity and direct tissue damage
- Immune effects: contact dermatitis in humans, sensitization in rats
- Reproductive and developmental toxicity in mice, incl. testicular degeneration and decreased sperm
- Cancer in animals and humans after prolonged exposures

Cancer Effects of Hexavalent Chromium

- Classified as a “known human carcinogen”
- Causes lung cancers in occupational exposures
- Other tumors (stomach, liver) increased in occupationally exposed humans
- Damages DNA and is mutagenic
- Stomach cancer in mice after exposure in drinking water

Reasons for Considering Hexavalent Chromium an Oral Carcinogen

- Chemicals which produce cancer by one exposure route are assumed to produce cancer by other routes unless compelling evidence to the contrary
- Cancer evidence in this case by both inhalation (human) and oral (experimental animals) routes
- Some evidence of excess cancers of the digestive tract and liver in chromium workers
- Cr VI can enter cells to damage DNA

The chromium PHG was developed to:

- Protect against cancer and all other health effects

It is based on:

- A study in mice given Cr VI in drinking water (Borneff et al., 1968)
- Benign and malignant stomach tumors in the mice
- A cancer risk assessment model which assumes no threshold for cancer

Calculation of the Chromium PHG

- Uses estimated cancer potency and assumes people drink 2 L/day of water for 70 years
- Assumes 7% of total Cr is Cr VI, based on data available in 1998
- Yields a PHG of 2.5 ppb for total Cr, based on a 10^{-6} cancer risk level of 0.2 ppb for Cr VI
- This level was judged to be low enough to protect against all non-cancer effects, with an adequate margin of safety

What if PHG levels are exceeded?

- Estimated health risk could exceed a "negligible" level, but still pose a very small risk
- Risk estimates assume a lifetime of exposure
- The PHG is not a “bright line,” but more of a guidepost
- Development of MCLs by DHS will consider the estimated risk, plus economics and feasibility
- Exceedance reports must be published by water agencies

Summary of Chromium PHG Development

- Required under Safe Drinking Water Act of 1996, based only on public health considerations
- Comprehensive literature review and data evaluation, subjected to extensive peer review
- Used Cr VI/III ratio data available in 1998
- Estimated health-protective level for total Cr of **2.5 ppb**, based on 1 in 1 million lifetime cancer risk
- Includes adequate margin of safety to protect against all other potential health effects.